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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/768,917 | 01/24/2001 | Alain P. Vicari | SF0896K | 5028 |

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

| EXAMINER |
|---|
| DEBERRY, REGINA M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 08/20/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/768,917 | VICARI ET AL. | |
| | Examiner | Art Unit | |
| | Regina M. DeBerry | 1647 | |

*-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --*

**Period for R ply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-36 and 67-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-36 and 67-69* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

***Status of Application, Amendments and/or Claims***

The amendment filed 11 March 2002 (Paper No. 10) has been entered in full. Claims 67-69 were added. Applicant states that claims 1-20 and 37-66 are to be cancelled without prejudice. The amendment filed 13 June 2002 (Paper No. 12) has been entered in full. Applicant's election without traverse of Group VI (claims 21-36) in Paper No. 10 is acknowledged.

Applicant's species election with traverse of viral antigens and Melan-A in Paper No. 10 is acknowledged. The traversal is on the grounds that claims 29 and 30 simply enumerate subtypes of antigens, defined by their origin (viral, bacterial or fungal). Applicants state that these three subtypes, by definition, share a feature, which makes them useful in the present methods, that is the ability to elicit an immune response. Applicant states that the arguments set forth in support for maintaining a Markush group consisting of "viral, bacterial and fungal" antigens, is equally applicable to support maintaining a Markush group consisting of a list of specific tumor-associated antigens. Applicant also cites MPEP 806.04(f) and *In re Harnisch.*

MPEP 803.02 (Restriction-Markush Claims) states that a Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). Thus, a search of the instant species would be directed to references, which would render the invention obvious, as well as references directed to anticipation of the invention. Furthermore, contrary to Applicant's assertion,

it is not necessarily true that all of the antigens and tumor-associated antigens cited will have the common functional utility, "the ability to elicit an immune response". The requirement is still deemed proper and is therefore made FINAL.

**Upon additional consideration, further restriction of the elected invention under 35 U.S.C. 121 is required.**

Applicant has added new dependent claims 67-69. Applicant states that the claims do not fall outside the invention the Examiner has classified as Group VI, consisting of claims 21-36. Applicant states that as claim 35 introduces the additional method step of administering an activating agent with the chemokine, no additional burden is presented by the enumeration of specific embodiments of said activating agent. This is not found persuasive for the reasons listed below.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

X. Claims 21-36 and 67, drawn in part to a method of enhancing an immune response in a mammal comprising administering MCP-4 and activating agent, TNF$\alpha$, classified in class 514, subclass 2.

XI. Claims 21-36 and 67, drawn to in part to a method of enhancing an immune response in a mammal comprising administering MCP-4 and activating agent, anti-CD-40 antibody, classified in class 424, subclass 134.1.

XII. Claims 21-36 and 68, drawn to in part to a method of enhancing an immune response in a mammal comprising administering MCP-4 and activating agent, RP-105, classified in class 514, subclass 2.

XIII. Claims 21-36 and 69, drawn to in part to a method of enhancing an immune response in a mammal comprising administering MCP-4 and activating agent, nucleic acid containing unmethylated CpG motif, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Groups X-XIII are different methods because they require different ingredients, process steps, and/or endpoints. These inventions require different method steps to accomplish the use, wherein each is not required, one for another. For example, Group X requires search and consideration of administration of TNF$\alpha$, which is not require by the other invention. Group XI requires search and consideration of administration of antibodies, which is not require by the other invention. Group XII requires search and consideration of administration of RP-105, which is not require by the other invention. Group XIII requires search and consideration of administration of nucleic acids, which is not require by the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary L. Kunz

RMD
August 18, 2002